This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 51-R-0079 CUSTOMER NO. 21555

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

GENE LOGIC LABORATORIES INC
610 PROFESSIONAL DRIVE
GAITHERSBURG, MD 20879
(301) 987-1700

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS*(sites)*

See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use APHIS FORM 7023A)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic,analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)*	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs	0	263	176	1	440
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	141	406	3	550
7. Hamsters	0	0	0	0	0
8. Rabbits	0	1663	45	5	1713
9. Non-Human Primates	0	426	36	2	464
10. Sheep	0	0	0	0	0
11. Pigs	0	12	0	0	12
12. Other Farm Animals	0	0	0	0	0
13. Other Animals	0	0	0	0	0

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all the exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional official)
I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL [redacted] b6,b7c

DATE SIGNED 10.19.6

APHIS FORM 7023 (AUG 91) (Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

ANNUAL REPORT OF RESEARCH FACILITY

Certificate Number: 51-R-0079
Customer Number: 21555

3. Reporting Facility

Gene Logic Laboratories Inc.
(Formerly Therimmune Research Corporation)

b2, b7f

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY

Column E Explanation (Amendment to 2005 Report)

I. **DOGS**

Species: Beagle Dog
Stud: B4
Animal Number: B4
Test Group/Sex: 4F
Justification:
Current Food and Drug Administration (FDA) policy requires the use of rodent and non-rodent species for chemical compounds when data will be submitted for Individual New Drug application. Study designs follow the Good Laboratory Practice (GLP) for Non-clinical Laboratory Studies (FDA 21 CFR Part 58) and are based on International Committee on Harmonization (ICH) Harmonized Tripartite Guidelines of Technical Requirements for Registration of Pharmaceuticals for Human Use, Organisation for Economic Co-operation and Development Guidelines for Testing of Chemicals(OECD), and/or Japan Ministry of Health, Labor, and Welfare (MHLW) Agency for Healthcare, Research and Quality Agency for Toxic Substances. Because this study was conducted in accordance with regulatory guidelines, alternatives could not be considered. Route of administration was based on intended delivery route for humans.
Summary:
This animal participated in B4 The purpose of this study was to evaluate the (b)(4) B4 of a test article (b)(4) to dogs (b)(4) As with all of our protocols, the following statement was included, "Any animals showing signs of severe debility, toxicity, or if death appears imminent will be euthanized for humane reasons". This statement is included to allow intervention aimed to alleviate pain or distress.
The animal had completed (b)(4) and death occurred on Study Day B4 clinical observation, this dog showed (b)(4) The veterinarian and the Study Director were contacted however the animal died before euthanasia could be administered.

ANNUAL REPORT OF RESEARCH FACILITY

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OCT 30 2006

II. MONKEYS

Species: Monkey
Study: 05051 B4
Animal Number: Temp #30 B4
Test Group/Sex: N/A/Male
Justification:
B4 and was assigned to B4 The animal was 19 days in to a 30 day acclimation period when he was found dead.
Summary:
B4 B4. On 4/18/06, the animal was found moribund. The technician immediately contacted appropriate personnel for approval to euthanize, but the animal died prior to intervention.

Species: Monkey
Study: B4
Animal Number: B4
Test Group/Sex: 1/M
Justification:
Current Food and Drug Administration (FDA) policy requires the use of rodent and non-rodent species for chemical compounds when data will be submitted for Individual New Drug application. Study designs follow the Good Laboratory Practice (GLP) for Non-clinical Laboratory Studies (FDA 21 CFR Part 58) and are based on International Committee on Harmonization (ICH) Harmonized Tripartite Guidelines of Technical Requirements for Registration of Pharmaceuticals for Human Use, Organisation for Economic Co-operation and Development Guidelines for Testing of Chemicals(OECD), and/or Japan Ministry of Health, Labor, and Welfare (MHLW) Agency for Healthcare, Research and Quality Agency for Toxic Substances. Because this study was conducted in accordance with regulatory guidelines, alternatives could not be considered. Route of administration was based on intended delivery route for humans.
Summary:
This animal was part of a B4 (b)(4) (b)(4). (b)(4). The veterinarian was called and he immediately began CPR and placed the animal on oxygen. (b)(4) (b)(4). but the animal died approximately 3 minutes later. (b)(4) (b)(4)

III. RABBITS

Species: Rabbit
Study: B4
Animal Number: 3939
Test Group/Sex: 2F
Justification:
Current FDA policy requires the use of rodent and non-rodent species for chemical compounds when data will be submitted for Individual New Drug application. Study designs follow the GLP for Non-clinical Laboratory Studies (FDA 21 CFR Part 58) and are based on ICH Tripartite Guidelines, OECD, and/or MHLW. Because this study was conducted in accordance with regulatory guidelines, alternatives could not be considered.
Summary:
This animal was part of (b)(4) study to determine test article effects on B4 was documented. (b)(4)'. A Vet request was submitted on 9/20/06. The veterinarian came to look at the animal, and placed the animal on the (b)(4)

When the veterinarian picked the animal up to place her back in the cage, she had a (b)(4) and passed away immediately.

Species: Rabbit
Study: (b)(4)
Animal Number: 3849
Test Group/Sex: 6F
Justification:
Current FDA policy requires the use of rodent and non-rodent species for chemical compounds when data will be submitted for Individual New Drug application. Study designs follow the GLP for Non-clinical Laboratory Studies (FDA 21 CFR Part 58) and are based on ICH Tripartite Guidelines, OECD, and/or MHLW. Because this study was conducted in accordance with regulatory guidelines, alternatives could not be considered.
Summary:
This animal was part of a (b)(4) study to determine test article effects on B4 B4 the animal was observed as "Normal" at the PM mortality check. and was found dead at the AM Mortality check on 7/4/06. It is GLL's intention to alleviate any pain or suffering whenever possible; however there were no indications that this animal was moribund.

Species: Rabbit
Study: (b)(4)
Animal Number: 6380
Test Group/Sex: 3F
Justification:
Current FDA policy requires the use of rodent and non-rodent species for chemical compounds when data will be submitted for Individual New Drug application. Study designs follow the GLP for Non-clinical Laboratory Studies (FDA 21 CFR Part 58) and are based on ICH Tripartite Guidelines, OECD, and/or MHLW. Because this study was conducted in accordance with regulatory guidelines, alternatives could not be considered.
Summary:
This animal was part of a B4 study to determine test article effects on B4 but died shortly B4 B4

Species: Rabbit
Study: (b)(4)
Animal Number: 6397
Test Group/Sex: 5F
Justification:
Current FDA policy requires the use of rodent and non-rodent species for chemical compounds when data will be submitted for Individual New Drug application. Study designs follow the GLP for Non-clinical Laboratory Studies (FDA 21 CFR Part 58) and are based on ICH Tripartite Guidelines, OECD, and/or MHLW. Because this study was conducted in accordance with regulatory guidelines, alternatives could not be considered.
Summary:
This animal was part of a B4 to determine test article effects on B4 ut died shortly after administration of B4

Species: Rabbit
Study: B4
Animal Number: 12615
Test Group/Sex: 4F
Justification:
Current FDA policy requires the use of rodent and non-rodent species for chemical compounds when data will be submitted for Individual New Drug application. Study designs follow the GLP for Non-clinical Laboratory Studies (FDA 21 CFR Part 58) and are based on ICH Tripartite Guidelines, OECD, and/or MHLW. Because this study was conducted in accordance with regulatory guidelines, alternatives could not be considered.
Summary:
This animal was part of a protocol designed to compare B4 B4 B4 At the AM mortality check, the animal was found dead. B4 B4

IV. GUINEA PIGS

Species: Guinea Pig
Study: B4
Animal Number: 13948
Test Group/Sex: 1F
Justification:
This study was conducted under current GLL SOP's and in the spirit of GLP's. This study was conducted under an Inter-Institutional agreement, and was performed by technicians from both facilities.
Summary:
This animal was involved in a B4 study. The animal was dosed on (b)(4) Dosing B4 B4 (b)(4) It cannot be determined what specifically caused the clinical signs on this animal. It is GLL's intention to alleviate any pain or suffering whenever possible; however there were no clear indications that this animal was moribund.

Species: Guinea Pig
Study: (b)(4)
Animal Number: 14040
Test Group/Sex: 3F
Justification:
This study was conducted under current GLL SOP's and in the spirit of GLP's. This study was conducted under an Inter-Institutional agreement, and was performed by technicians from both facilities.
Summary:
This animal was involved in b4 study. b4 , the wrapping was removed from the animal, and the animal appeared B4 B4 (b)(4) The Study Director and Veterinarian were contacted immediately. However the animal died prior to the veterinarian arriving. It cannot be determined what caused the sudden death of this animal, although

it may have been B4 related. It is GLL's intention to alleviate any pain or suffering whenever possible; however there were no clear indications of toxicity or distress associated with this animal prior to that afternoon.

Species: Guinea Pig
Study: B4
Animal Number: 14359
Test Group/Sex: 2F
Justification:
This study was conducted under current GLL SOP's and in the spirit of GLP's. This study was conducted under an Inter-Institutional agreement, and was performed by technicians from both facilities.
Summary:
This animal was involved in B4. The animal b4 B4 The animal recovered from anesthesia, but was not very (b)(4). On B4 the animal was found dead. No other clinical signs were observed. It cannot be determined what caused the sudden death of this animal, although it may have been B4 It is GLL's intention to alleviate any pain or suffering whenever possible; however there were no clear indications of toxicity or distress associated with this animal.